Rev 1: September 2018
FSN Ref: 800012097 FSCA Ref: 800012097

Date: 10. Aug. 2023

Urgent Field Safety Notice
Erytra Eflexis® analyzer

Potential misinterpretation of results from a multiple techniques profile automatically cancelled and rescheduled due to an error situation

For Attention of: Distributors and Health Care Professionals, who are using Erytra Eflexis analyzer Software version 3.0.1.

Contact information

For additional information, please contact your local service representative at

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1. **Information on Affected Devices**	
1.	1. Device Type(s)
	Automated Blood Typing System
1.	2. Commercial name(s)
	Erytra Eflexis
1.	3. Unique Device Identifier(s) (UDI-DI)
	08436583730942
1.	4. Primary clinical purpose of device(s)
	Erytra Eflexis is a fully-automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing gel card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Compatibility Tests and Direct Antiglobulin Tests.
1.	5. Device Model/Catalogue/part number(s)
	ref. 210600
1.	6. Affected serial or lot number range
	Software version 3.0.1

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	Grifols received a complaint in which during processing a profile that includes multiple techniques, a card lost error arose. After this, the affected technique of the profile is cancelled and the instrument rescheduled it again. Afterwards, even the instrument has only the results from one of the techniques, the analyzer gave an interpretation that can be incorrect.
2.	2. Hazard giving rise to the FSCA
	The analyzer may give incorrect interpretations of a profile that includes multiple techniques under certain conditions.
2.	3. Probability of problem arising
	The issue can only occur in a profile with more than one technique and with common interpretation between those techniques. The issue occurs due to a mismanagement of different concurrent software tasks during an automatic reschedule of the technique driven after an error situation. If there is no common interpretation between techniques, the issue will lead to a partial result reported. The probability of occurrence is deemed to be very low as two software actions must happen at the same time.
2.	4. Predicted risk to patient/users
	An incorrect interpretation of the results by the analyzer can compromise patient safety if went undetected by the Laboratory Users.
2.	5. Further information to help characterise the problem
	The issue affects Erytra Eflexis Software version 3.0.1. The occurrence of this issue is improbable in previous software versions based on the investigation conducted at Grifols.

2.	6. Background on Issue
	During processing of a profile with multiples techniques with common interpretation, if any of the profiles is cancelled due to an error, the software during reschedule can mismanage the different tasks and not provide all the results, interpreting only some of the available data and providing an incorrect interpretation. This mismanagement occurs due to the concurrency of different tasks at the same time, that can occur randomly, and it has been found to be very unlikely.
2.	7. Other information relevant to FSCA
	Grifols is working on a new software version to solve this issue.

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None From now on and until updating the SW version, please review and validate all results of profiles with multiple techniques and common interpretations manually to ensure that all the profiles have been correctly executed and that the analyzer gave the correct interpretation. Your local service representative can provide support to confirm the use or not of multiple technique profiles on your instrument. If you are not using profile with multiple techniques, no actions are required from your side.	
3.	2. By when should the action be completed?	The action has to be conducted immediately after receipt of this FSN and until a new software version is available to solve the issue.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Grifols will conduct a review of your analyzer log files to detect any potential affected results since the installation of version 3.0.1 in your analyser and will provide a letter with the output of the analysis.	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Grifols is working on a new software version to solve this issue. Additionally, a review of the customer analyzer log files will be conducted to detect any potential affected result since the installation of version 3.0.1.	

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Diagnostic Grifols S.A.**
	b. Address	**Passeig Fluvial, 24, 08150, Parets Del Vallès, Spain**
	c. Website address	**www.grifols.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	[redacted] **Technical Director** [redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.